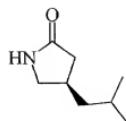
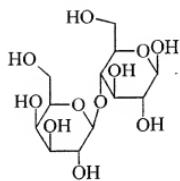


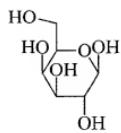
Pregabalin



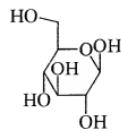
Pregabalin Lactam



β -D-Lactose



β -Galactose



β -Glucose

Figure 1

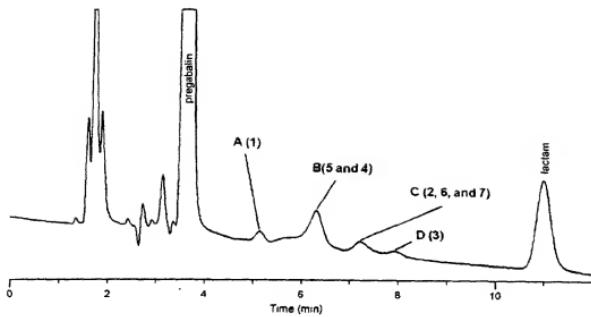


Figure 2. HPLC Chromatogram of Pregabalin 25-mg Capsule Stored at 40°C/75% RH for 6 Months (Original Method) HPLC Conditions: Column: Waters μ -Bondapak 10 μ C18, 300 \times 3.9 mm ID; Mobile Phase: 550:350:100:1 H₂O:MeOH:CH₂ON:pH 7.0 Phosphate Buffer; Flow Rate: 1.0 mL/min; Detection: 210 nm; Temperature: Ambient; Compounds: as defined in Scheme 3

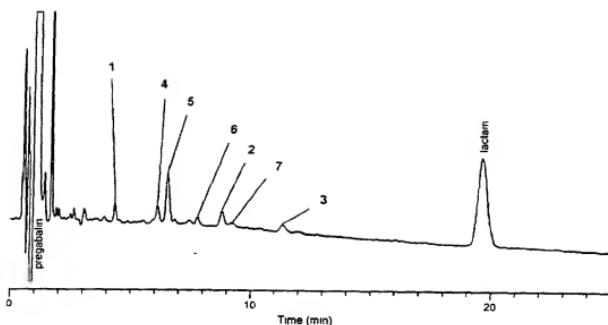


Figure 3. HPLC Chromatogram of Pregabalin 25-mg Capsules Stored at 40°C/75% RH for 6 Months (Modified Method) HPLC Conditions; Column: Phenomenex Luna C18 (2) 100 × 4.6 mm ID, 3 μ ; Mobile Phase: 85:15 0.05% Formic Acid:CH₃CN; Flow Rate: 1.5 mL/min; Detection: 210 nm; Temperature: Ambient; Compounds: as defined in Scheme 3